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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,155	08/31/2001	Daniel S. Pilch	266/300	1597

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/21/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/945,155

Applicant(s)

PILCH ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 1, 10, and 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Applicant's election without traverse of invention group II, claims 2-9, 11 and 12 in Paper No. 7 is acknowledged. Applicant's election with traverse of neomycin as the elected species in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the disclosed 5 species should be examined fully because they are within a Markush group. This is not found persuasive because the disclosed five species are not in a proper Markush group. It is well settled patent law that a Markush group must contain an immutable structural core responsible for the claimed activity. Applicant fails to provide an immutable central core structure for the proffered claims thereby presenting an improper Markush group for examination. Failure to link the claimed compounds with an immutable core structure results in claims reading on more than one invention, requiring restriction under 35 USC 121.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on elected species.

### ***Claim Rejections 35 U.S.C. §112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-9 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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3. Claim 2 recites the limitation "the anti-viral agent" in line 3. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 11 recites the limitation "the antiviral agent" in line 2. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 6 and 8 recite a particular ratio of neomycin and RNA-DNA hybrid substrates; fail to define what the ratio is, e.g., by weight, by volume, or by mole. The claims are indefinite as to the amount of neomycin encompassed thereby.
6. Claim 2 and 11 recite the method comprises a step of "targeting," however, the specification or the claims does not specify what actions would be encompassed by the word "targeting" The claims are indefinite as to the actual action of the step encompassed thereby.

***Claim Rejections 35 U.S.C. 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-9 and 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee et al. in view of Furfine et al. (IDS), and Hammer
9. Coffee et al. teaches that neomycin is useful for stabilization of RNA-DNA hybrid complex presented in cellular or viral protein, to suppress the transcription and/or translation of specific gene. See the abstract.
10. Coffee does not teach expressly the virus has reverse transcriptase, e.g., HIV virus, or the particular concentration of neomycin.

However, it would have been prima facie obvious to employ the method to suppress HIV reverse transcriptase because it is a known method to suppress the activity of HIV. See, e.g., Furfine, the abstract, and pages S4-S5 in Hammer. Further, the optimization of a result effective parameter, e.g., the effective amount of neomycin herein, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

11. Claims 2-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 5,534,408).
12. Green teaches that neomycin is useful in inhibition of HIV replication, See, particularly, the abstract, and the claims.
13. Green does not teach expressly for “targeting” RNA-DNA hybrid substrates, or the particular amounts of neomycin herein.

However, it would have been prima facie obvious to one of ordinary skill in the art, at the time the invention was made, to contact HIV virus, either in vitro, or in vivo, with effective amount of neomycin for inhibiting the replication of HIV because neomycin is known to be useful for inhibiting the replication of HIV. Regarding to the limitation “targets and binds to the RNA-DNA hybrid substrate,” note the instant claims are directed to effecting a biochemical pathway with an old and well known compounds. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant’s attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” The ultimate utility for the claimed compounds

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is old and well known, i.e., for inhibiting the replication of HIV, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Further, the optimization of a result effective parameter, e.g., the effective amount of neomycin herein, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

 SHENGJUN WANG  
PATENT EXAMINER

Shengjun Wang

May 14, 2003